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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/522,081 | 02/03/2006 | Cinzia Lanzi | M400-F111 | 7569 |

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| EXAMINER | |
|---|---|
| TEALE, MICHAEL J | |

| ART UNIT | PAPER NUMBER |
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| 1614 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/522,081 | LANZI ET AL. | |
| | Examiner | Art Unit | |
| | Michael J. Teale Ph.D. | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant is advised that "Use of" claims are not a U.S. statutory class of invention; thus, the claims are interpreted as both method (or process) claims and as compound (or product) claims and will be listed in groups of each type.

The examiner believes that applicant erred via a typo in claim 22 where applicant refers back to claim 19 when applicant obviously meant to refer to claim 21. Accordingly, the restriction requirement will reflect the examiner's assumption.

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

> Group I, claims 1-18, drawn to method for the treatment of tumors using a medicament containing 1,3-dihydro-5,6-dimethoxy-3-[(4- hydroxyphenyl)methylene]-2H-indol-2-one or of non-toxic salts or isomers thereof.
>
> Group II, claim 1-24 are drawn to compositions and kits containing 1,3-dihydro-5,6-dimethoxy-3-[(4- hydroxyphenyl)methylene]-2H-indol-2-one or of non-toxic salts or isomers thereof.

The inventions listed in Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: the method(s) of Group I treat tumors (where

treatment methods are not contained in Group II), and tumors may be malignant or not, arrise from numerous different tissues, and reside just about anyway in the body one can imagine, which requires different modes of treatment or routes of medicament application. The compositions of the Group II are products not produced in Group I, and require a selection from any number of anti-tumor or anti-cancer agents having different chemical structures, modes of action, and biological and physiological effects.

***Species Election***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

tyrosine kinases, oncoprotein of the Ret family, activated sequence mutations, tumors, cancers, anti-tumor or anti-cancer agent.

Applicant is required, in reply to this action, to elect a single species by:

Should applicant elect the Group I method claims 1-18 then applicant is to elect either a tyrosine kinase (for example tyrosine kinases in claim 1) or an oncoprotein of the Ret family. If applicant elects an oncoprotein of the Ret family then in addition applicant is to elect a specific member of the Ret family oncoproteins. In addition if applicant elects a specific Ret oncoprotein applicant is to further elect an activated sequence mutation (for example claims 3-4), and a tumor type, or a cancer type: if applicant's

election discloses a genus then applicant is to elect a specific member of the genus (for example if applicant elected leukemias (claim 11) then applicant is required to name a specific type of leukemia),

to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Applicant **is required**, in reply to this action, **to elect a single species** by: should applicant elect the Group II compositions claims 1-24 then applicant is to elect either a tyrosine kinase (for example tyrosine kinases in claim 1) or an oncoprotein of the Ret family. If applicant elects an oncoprotein of the Ret family then in addition applicant is to elect a specific member of the Ret family oncoproteins. In addition if applicant elects a specific Ret oncoprotein applicant is to further elect an activated sequence mutation (for example claims 3-4), as well as, a tumor type, or a cancer type: if applicant's election discloses a genus then applicant is to elect a specific member of the genus (for example if applicant elected leukemias then applicant would name a specific type of leukemia). In addition, applicant is required to elect an anti-tumor or anti-cancer agent (for example claims 22 and 24): should applicant's election disclose a genus then applicant is to elect a specific member of the genus (for example if applicant elected leukemias then applicant is required to name a specific type of leukemia),

to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claims 1-18: tyrosine kinases, oncoprotein of the Ret family, activiated sequence mutations, tumors, and cancers; Claims 19 -24 anti-tumor or ant-cancer agent

The following claim(s) are generic: claims 1-24

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species represent numerous different compounds, classes of compounds, sequences, proteins, and diseases affecting many different biological and physiological systems.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found

allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Furthermore the examiner may find if necessary to further restrict the elected invention once depending on applicant's election and the state of the associated art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Teale Ph.D. whose telephone number is (517)-272-6897. The examiner can normally be reached on 7:30 am to 4:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJT

12/8/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER